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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/577,983

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John C. Herr

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UNIVERSITY OF VIRGINIA PATENT FOUNDATION
250 WEST MAIN STREET, SUITE 300
CHARLOTTESVILLE, VA 22902

EXAMINER

HAND, MELANIE JO

ART UNIT

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06/10/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,983	Applicant(s) HERR ET AL.	
	Examiner MELANIE J. HAND	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 6-93 is/are pending in the application.
- 4a) Of the above claim(s) 58-81 and 83-89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-38,40-57,82 and 90-93 is/are rejected.
- 7) ☒ Claim(s) 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 7, 2010 has been entered.

Response to Arguments

2. Applicant's arguments with respect to claims 1, 2, 6-57, 82 and 90-93 have been considered but are moot in view of the new ground(s) of rejection prompted by applicant's amendment to the claims.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 7,10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "at least substantially flat" is not defined in any way in applicant's specification. Thus, what is meant by this phrase is unclear and the scope is thus indeterminate, rendering the claim indefinite.

Claim Rejections - 35 USC § 102

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5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 2, 6-10, 14-17, 19-25, 32-38, 40-46, 50-57, 82 and 90-93 are rejected under 35 U.S.C. 102(e) as being anticipated by Prien et al (U.S. Patent No. 6,864,046).

With respect to **claim 1**: Prien discloses a human glans-penis-accommodating device for collecting all fractions of ejaculated semen sample received from the glans penis. With regard to the limitation “after masturbation and/or post-coital interruption” the device of Prien collects semen from a human penis, thus it is fully functional to collect semen received after masturbation or post-coital interruption. The device comprises the following: a chamber 28, said chamber comprising a distal end that is distal with respect to the glans penis, a proximal end proximal to said glans penis, and a conduit extending between said distal end and proximal end (Fig. 1); said proximal end having a rim defining an aperture in the form of an artificial vagina; said distal end having a surface that encloses said conduit; at least a portion of said conduit proximal to said proximal end having a tapered shape (specifically conical) tapering radially inward and defining a tapered section, whereby said tapered section accommodates the head of the glans penis; at least a portion of said conduit proximal to said distal end adapted for receiving the semen ejaculated from the glans penis, said receiving portion defining a reservoir section for the semen; and wherein said tapered accommodation section is configured to

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prevent loss of any fractions of semen during ejaculation; and said reservoir section is configured to prevent loss of any fractions of semen during ejaculation, inasmuch as Prien discloses that all fluids ejaculated are routed to the collection vessel 20. (Col. 9, lines 13-24)

With respect to **claim 2**: The tapered accommodation section is configured to the general external image of the head of the glans penis inasmuch as it accepts the entire head of the penis and is an artificial vagina, which is interpreted herein as referring to its shape as simulating an actual human vagina which is configured to the general external image of the head of the glans penis.

With respect to **claims 6,9**: The enclosure surface, i.e. the wall of the conical chamber 28, is adapted to allow said chamber to stand upward on a surface inasmuch as the larger base of the cone shape supports the remainder of the device when the cone is rested on said surface.

With respect to **claims 7,10**: The enclosure surface disclosed by Prien is considered herein to be at least substantially flat inasmuch as it is a conical funnel made from what is considered herein to be a flat sheet material. (Fig. 1)

With respect to **claim 8**: As can be seen in Fig. 1 of Prien, the longest cross-section of said reservoir section (adjacent gasket 42 and Y-tube 32) is equal to or less than the shortest cross-section of the tapered accommodation section adjacent the proximal end of the chamber 28.

With respect to **claim 14**: The device disclosed by Prien further comprises at least one protruding member, Y-tube 32 disposed on said chamber, said protruding member adapted to

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allow said chamber to stand upward on a surface inasmuch as the two branches of the Y-tube would provide support for, and distribute the weight of, the chamber 28 when rested on a surface.

With respect to **claim 15**: The protruding member 32 disclosed by Prien comprises at least one leg. (Fig. 1)

With respect to **claim 16**: The protruding member comprises a collar, gasket 42, surrounding at least a portion of said chamber 28. (Col. 9, lines 34-37)

With respect to **claim 17**: As can be seen in Fig. 1 of Prien, the longest cross-section of said reservoir section (adjacent gasket 42 and Y-tube 32) is equal to or less than the shortest cross-section of the tapered accommodation section adjacent the proximal end of the chamber 28.

With respect to **claim 19**: The tapered accommodation section disclosed by Prien is bell-shaped. (Fig. 1)

With respect to **claim 20**: Applicant has not explicitly disclosed a meaning for the term “olive-shaped”, therefore the claim is given its broadest reasonable interpretation. The tapered accommodation section disclosed by Prien is considered herein to be olive-shaped, as it has a generally elliptical, arcuate or circular profile.

With respect to **claim 21**: Applicant has not explicitly disclosed a meaning for the term “hemispherical-shaped”, therefore the claim is given its broadest reasonable interpretation. The

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tapered accommodation section disclosed by Prien is considered herein to be hemispherical-shaped inasmuch as its conical/bell and ellipsoid shape approximates a hemisphere due to the nature of a conical, bell or ellipsoid shape, i.e. smaller or converged at one end and flaring as one progresses away from the shortest cross-section.

With respect to **claim 22**: As stated *supra*, Prien discloses that the chamber is an artificial vagina, interpreted herein as referring to its shape which mimics that of an actual vagina or vaginal opening, which is elliptical. Thus it is the examiner's position that said tapered accommodation section is ellipsoid-shaped.

With respect to **claim 23**: The tapered accommodation section 28 disclosed by Prien is multifaceted-shaped inasmuch as it is a conical element with a base and side wall, i.e. it has multiple facets.

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With respect to **claim 24**: The tapered accommodation section disclosed by Prien is cone-shaped.

With respect to **claim 25**: The tapered accommodation section comprises at least one wall, wherein said at least one wall comprises a shape, namely curved.

With respect to **claim 32**: The device disclosed by Prien is used for semen analysis laboratories inasmuch as Prien discloses that the collection vessel is used for collecting samples for comparative study. (Abstract)

With respect to **claim 33**: The device disclosed by Prien further comprises a port for receiving Y-tube 32 disposed on said reservoir section to allow for drainage or removal of the semen to collection vessel 20.

With respect to **claim 34**: The device disclosed by Prien further comprises a port for receiving Y-tube 32 disposed on said reservoir section to allow for access or communication to the semen via Y-tube 32.

With respect to **claims 35,37**: The chamber 28 is integrally formed inasmuch as it is of a one-piece construction.

With respect to **claims 36,38**: Prien discloses that the device is integrally formed. (Col. 9, lines 37-42)

With respect to **claim 40**: The device disclosed by Prien further comprises an adapter section, namely junction 34.

With respect to **claim 41**: The device disclosed by Prien further comprises at least one handle disposed on said device inasmuch as either branch of Y-tube 32 is fully functional as a handle.

With respect to **claim 42**: The handle comprises a branch of Y-tube 32, i.e. a protrusion.

With respect to **claim 43**: The device disclosed by Prien further comprises at least one grip

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ridge disposed on said device in the form of the portion of y-tube 32 between the junction 34 and the spilt of the branches of the tube.

With respect to **claim 44**: The adapter section 34 disclosed by Prien comprises a collar, namely a gasket.

With respect to **claim 45**: The adapter section 34 is configured to accommodate the glans penis inasmuch as it is part of the reservoir section of artificial vagina 28 which is configured to accommodate the glans penis.

With respect to **claim 46**: The collar 42 comprises a jacket.

With respect to **claim 50**: The reservoir section at least partially comprises at least one communication channel defined by the walls of the artificial vagina 28.

With respect to **claims 51,54**: The at least one communication channel comprises a channel defined by the wall of the artificial vagina 28.

With respect to **claim 52**: The device disclosed by Prien further comprises a port for receiving Y-tube 32 disposed on said reservoir section to allow for drainage or removal of the semen to collection vessel 20.

With respect to **claim 53**: The device disclosed by Prien further comprises a port for receiving Y-tube 32 disposed on said reservoir section in communication with the at least one

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communication channel.

With respect to **claim 55**: The device disclosed by Prien further comprises at least one handle disposed on said device inasmuch as either branch of Y-tube 32 is fully functional as a handle.

With respect to **claim 56**: The handle comprises a branch of Y-tube 32, i.e. a protrusion.

With respect to **claim 57**: The device disclosed by Prien further comprises at least one grip ridge disposed on said device in the form of the portion of y-tube 32 between the junction 34 and the spilt of the branches of the tube.

With respect to **claim 82**: The device disclosed by Prien further comprises a port disposed on said collection device that receives Y-tube 32. (Fig. 1)

With respect to **claim 90**: The device disclosed by Prien further comprises a base, collection vessel 20, in communication with said device, said base considered herein to be adapted to allow said chamber to stand upward on a surface.

With respect to **claim 91**: The communication comprises a connector, Y-tube 32.

With respect to **claim 92**: The connector 32 disclosed by Prien comprises at least one leg or stem.

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With respect to **claim 93**: The connector 32 disclosed by Prien comprises a joining or adhesive means, namely gasket 42.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 11-13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prien et al ('046).

With respect to **claim 11**: Prien discloses at least in Fig. 4 that the longest cross-section of said reservoir section is less than or equal to the shortest cross-section of the tapered section and thus does not disclose an embodiment in which the longest cross-section greater than the shortest cross-section of the tapered accommodation section. However, applicant has not

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disclosed any criticality for this limitation. Therefore, this limitation is considered herein to be directed to an obvious design choice, as either a cross section that is less than or equal to the accommodation section cross-section, or a cross-section that is greater, will still produce a tapered effect that meets the structural limitations of the tapered section as claimed and still facilitate the collection of semen equally well regardless of the relationship between the distal cross-section and the tapered accommodation section. It would therefore be obvious to one of ordinary skill in the art to modify the device of Prien such that the longest cross-section of the reservoir section is greater than the shortest cross section of the tapered section with a reasonable expectation of success to provide a device that collects semen as intended.

With respect to **claim 12**: The enclosure surface, i.e. the wall of the conical chamber 28, is adapted to allow said chamber to stand upward on a surface inasmuch as the larger base of the cone shape supports the remainder of the device when the cone is rested on said surface.

With respect to **claim 13**: The enclosure surface disclosed by Prien is considered herein to be at least substantially flat inasmuch as it is a conical funnel made from what is considered herein to be a flat sheet material. (Fig. 1)

With respect to **claim 18**: Prien discloses at least in Fig. 4 that the longest cross-section of said reservoir section is less than or equal to the shortest cross-section of the tapered section and thus does not disclose an embodiment in which the longest cross-section greater than the shortest cross-section of the tapered accommodation section. However, applicant has not disclosed any criticality for this limitation. Therefore, this limitation is considered herein to be directed to an obvious design choice, as either a cross section that is less than or equal to the

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accommodation section cross-section, or a cross-section that is greater, will still produce a tapered effect that meets the structural limitations of the tapered section as claimed and still facilitate the collection of semen equally well regardless of the relationship between the distal cross-section and the tapered accommodation section. It would therefore be obvious to one of ordinary skill in the art to modify the device of Prien such that the longest cross-section of the reservoir section is greater than the shortest cross section of the tapered section with a reasonable expectation of success to provide a device that collects semen as intended.

10. Claims 26, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prien et al ('046) in view of Bar-Ami et al (U.S. Patent No. 6,129,214).

With respect to **claims 26,27**: Prien does not disclose that the device further comprises a cover disposed on said chamber. Bar-Ami discloses a semen collection container in the collective form of outer cell 100 and inner cell 110 placed inside outer cell 100, wherein the outer cell and inner cell having a cover in the form of lid 130. Bar-Ami discloses that the lid prevents foreign debris from entering either the inner cell or the outer cell. ('214, Figs. 6a, 6b, Col. 10, lines 3-8, 62-64) Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Prien such that the device further comprises a cover disposed on said chamber as disclosed by Bar-Ami to prevent foreign debris from entering the chamber.

11. Claims 28, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prien et al ('046) in view of Velazquez (U.S. Patent No. 6,699,226).

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With respect to **claim 28**: Prien does not disclose that the device further comprises a tracking medium. Velazquez discloses a kit for collecting semen comprising a container defining a chamber upon which a region for storing desired information is disposed. Since the device of Velazquez seeks to solve a similar problem in the art to that with which applicant is concerned (i.e. provide a means for collecting semen) and the bar code disclosed by Velazquez provides a means for storing uniquely identifying information to distinguish samples from one another for proper analysis, it would be obvious to one of ordinary skill in the art to modify the device of Prien so as to further comprise a tracking medium as disclosed by Velazquez with a reasonable expectation of success to ensure samples are properly identified and analyzed.

With respect to **claim 29**: Prien does not disclose that the device further comprises a tracking medium. Velazquez discloses a tracking medium that comprises a printed bar code label. The motivation to modify the device of Prien so as to further comprise a tracking medium disposed on the chamber as disclosed by Velazquez is stated *supra* with respect to claim 28.

12. Claims 30, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prien et al ('046) in view of Ericsson et al (U.S. Patent No. 5,068,089).

With respect to **claim 30**: Prien does not disclose that the device further comprises a volume identification medium disposed on said chamber. Ericsson discloses a male fertility test kit comprising a collection tube having gradations. These gradations correlate volume of semen collected with the number of drops of testing reagent needed. ('089, Col. 8, line 65 – Col. 9, line 9) Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Prien such that the device further comprises a volume identification medium disposed on said

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container as disclosed by Douglas-Hamilton to notify the user of the volume collected for testing or other purposes.

With respect to **claim 31**: Prien does not disclose that the device further comprises a volume identification medium disposed on said chamber. The volume identification medium disclosed by Douglas Hamilton comprises a calibrated region adapted for indicating volume that correlates volume of semen collected to number of drops of test solution. The motivation to modify the device of Prien so as to further comprise a volume identification medium is stated *supra* with respect to claim 30.

13. Claims 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prien et al ('046) in view of Yap (U.S. Patent No. 6,113,532).

With respect to **claim 47**: Prien does not disclose that the adapter section comprises an ejaculation aid device. Yap discloses an ejaculation aid that can also be used as a collection device, similar to the adapter section 34 of artificial vagina 28 disclosed by Prien that accommodates a user's gland penis and at least temporarily collects semen. Yap discloses that the ejaculation aid promotes maximum cleanliness. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Prien by replacing the removable adapter section 38 with the ejaculation aid device disclosed by Yap to ensure maximum cleanliness during semen collection. ('532, Col. 2, lines 39,40)

With respect to **claim 48**: The adapter section of the device of Prien as modified by Yap comprises a stimulation device in the form of inflatable balloon 1 for stimulating the glans. The

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motivation to modify the device of Prien so as to comprise an ejaculation aid device as disclosed by Yap is stated *supra* with respect to claim 47. ('532, Col. 2, lines 39,40)

With respect to **claim 49**: The adapter section of the device of Prien as modified by Yap and disclosed by Yap is adapted to be held by the individual or a partner inasmuch as Yap discloses that the walls of the device can be manually squeezed during use. ('532, Col. 2, lines 34-38)

Allowable Subject Matter

14. Claim 39 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Reasons for Indicating Allowable Subject Matter

15. The following is a statement of reasons for the indication of allowable subject matter: with respect to claim 39, the tapered accommodation section and said reservoir section disclosed by Prien are continuous and of unitary construction as part fo artificial vagina 28 and therefore are not attachable to one another and/or detachable from one another. Further any modification to this device to meet this limitation would result in destruction of the artificial vagina, rendering the device unsatisfactory for its intended purpose. Thus the Prien reference teaches away from a tapered accommodation section and reservoir section that are attachable to one another and/or detachable from one another.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Primary Examiner, Art Unit 3761